REMARKS

This Amendment responds to the Office Action mailed January 18, 2008 in the above-identified application. Based on the foregoing amendments and the following comments, reconsideration and allowance of the application are respectfully requested.

Claims 1-34 are pending in the application. By this Amendment, claims 1, 3, 4, 7-9 and 27 have been amended. The amendment to claim 1 finds clear support in the original application at least at page 2, lines 16-25. The amendments to the other claims are for clarification. No new matter has been added.

The Examiner has objected to the listing of references in the specification as not being a proper Information Disclosure Statement. It is submitted that the references identified by the Examiner (GB-A-408856 and WO-A-98/53869) are not listed in Applicants' specification. Instead, these references are cited on pages 3 and 4 of Djupesland (WO 00/51672), cited by the Examiner. Accordingly, withdrawal of the objection is respectfully requested.

The Examiner has objected to the specification as referring to the claims. The specification has been amended to recite the language of original claim 1.

The Examiner has objected to the specification as lacking section headings. The specification has been amended to add section headings. Accordingly, withdrawal of the objections to the specification is respectfully requested.

The Examiner has rejected claim 27 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner asserts that the phrase "preferably" in claim 27 renders the claim indefinite. Claim 27 has been amended to delete the language alleged to be unclear, and withdrawal of the rejection is respectfully requested.

The Examiner has rejected claims 1-34 under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. The Examiner asserts that claims 1, 3, 4

and 7-9 positively recite a portion of the human body. Applicant submits that the claims do no more than describe the use of the claimed therapeutic aerosol device with the human body. Nonetheless, in order to advance prosecution of the application, the claims have been amended to recite that the elements of the claimed device are "configured" to function with a portion of the human body. Accordingly, withdrawal of the rejection under 35 U.S.C. §101 is respectfully requested.

The Examiner has rejected claims 1, 3-6, 8-10, 13-16 and 18-34 under 35 U.S.C. §103(a) as unpatentable over Chantrel et al. (EP 0507707) in view of Djupesland (WO 00/51672). Claims 2, 11, 12 and 17 are rejected under 35 U.S.C. §103(a) as unpatentable over Chantrel et al. in view of Djupesland as applied to claim 1, further in view of Brugger (DE 3238149). Claim 7 is rejected under 35 U.S.C. §103(a) as unpatentable over Chantrel et al. in view of Djupesland as applied to claim 1, further in view of Landis et al. (US 5,687,715). The rejections are respectfully traversed in view of the amended claims.

Chantrel discloses a therapeutic nebuliser which is equipped with an inhaler nozzle to be applied to a patient's nose. A constant aerosol flow is guided through the patient's nose, and pressure fluctuations are superimposed which are intended to cause the aerosol particles/droplets in the main aerosol flow to pass through the ostia and enter the paranasal sinuses. Chantrel fails to disclose the concept of providing a flow resistance device at the other of the alae of the patient's nose.

Djupesland discloses a device for delivering a substance to the nasal airway of a patient comprising, as a key feature, a closure unit for causing the closure of the oropharyngeal velum of the patient. Djupesland also teaches a delivery unit for delivering a gas flow entraining a substance to one of the nostrils of the patient but at such driving pressure as to flow around the posterior margin of the nasal septum and out of the other nostril of the patient. The delivery device also includes an outlet unit which includes an outlet for the gas flow and a flow resistor.

Amended claim 1 is directed to the therapeutic aerosol device comprising a nebuliser device including an aerosol generator to which a gaseous medium for the generation of a main aerosol flow may be supplied from a supply device, and a pressure connection device to supply pressure fluctuations which are superimposed on the main aerosol flow, a nosepiece configured to supply the aerosol into one of the two alae of the nose of a user connected to the nebuliser device, and a flow resistance device configured to be placed at the other of the two alae of the user's nose, the flow resistance device in use causing aerosol from the main aerosol flow having pressure fluctuations superimposed thereon to reach the paranasal sinuses of the user and to be deposited therein.

The claimed therapeutic aerosol device increases the deposition of an aerosol in the paranasal sinuses to enable therapeutically useful and predictable deposition in the paranasal sinuses through which there is no active flow. The invention is based on experimental investigations according to which, surprisingly, one of the most decisive factors is the flow resistance presented to the pressure fluctuations at the other nostril when an aerosol flow is supplied to one nostril. Only with a flow resistance device in place, the superimposed pressure fluctuations result in predictable aerosol deposition in the paranasal sinuses.

As indicated above, Chantrel discloses a therapeutic nebuliser wherein a constant aerosol flow is guided through the patient's nose and pressure fluctuations are superimposed which are intended to cause aerosol particles/droplets in the main aerosol flow to pass through the ostia and enter the paranasal sinuses. The Examiner acknowledges that Chantrel does not expressly disclose a flow resistance device for use in the other of the two alae of the user's nose. However, the Examiner asserts that Djupesland teaches this feature. Applicant's must respectfully disagree.

Djupesland discloses a device for delivering a substance to the nasal airway of a patient comprising, as a key feature, a closure unit for causing the closure of the oropharyngeal velum of the patient. Djupesland also teaches a delivery unit for delivering a gas flow entraining a

substance to one of the nostrils of the patient, but at such driving pressure as to flow around the posterior margin of the nasal septum and out of the other nostril of the patient.

Nevertheless, the key feature of the teaching of Djupesland is the closure of the oropharyngeal velum of the patient. This aspect is described numerous times in the specification of Djupesland. See for example Abstract; page 6, line 22; page 6, lines 26-28; page 6, line 30 to page 7, line 2; page 7, lines 4 and 5; page 7, third paragraph; page 7, line 25; page 9, lines 1 and 2; page 13, line 4; page 17, lines 22-30; page 18, line 25 to page 19, line 13; page 23, lines 4 and 5; page 24, lines 13-15; page 25, lines 13-15; page 26, lines 25 and 26; page 27, line 18; page 29, lines 14 and 15; page 30, lines 27 and 28 and independent claims 1 and 22.

In view of such a clear and repeated teaching of the need for closure of the oropharyngeal velum, Djupesland can not be considered to disclose a therapeutic aerosol device which relies on the effect of a flow resistance device in the other nostril of the patient. Much to the contrary, the skilled person would understand Djupesland as teaching that the outlet unit 36 shown in Fig. 3 can be used only in combination with the oral exhalation unit 20 and the delivery unit 22. According to Djupesland, a pressure differential across the velum sufficient to cause closure of the velum of the patient is required and only in combination with the latter effect, which is caused by the exhalation unit 20, would the outlet unit 36 be considered by the skilled person. There is no teaching in Djupesland to rely on the effects of the outlet unit alone.

These effects have been discovered by the inventors of the present application in experimental studies. Regarding the present invention, it is essential to take into consideration that the flow resistance device provided at the other of the two alae of the user's nose is sufficient to achieve predictable deposition of the aerosol in the desired areas without the requirement for a pressure differential across the velum, which is sufficient to cause closure of the velum of the patient. However, since this feature is stressed repeatedly in Djupesland, there is no teaching in Djupesland to provide a therapeutic aerosol device as defined by amended claim 1.

In summary, Chantrel and Djupesland, taken individually or in combination, do not disclose or suggest a therapeutic aerosol device including a flow resistance device configured to be placed at the other of the two alae of the user's nose, *the flow resistance device in use causing aerosol from the main aerosol flow having pressure fluctuations superimposed thereon to reach the paranasal sinuses of the user and to be deposited therein*, as required by amended claim 1. For at least these reasons, amended claim 1 is clearly and patentably distinguished over Chantrel in view of Djupesland, and withdrawal of the rejection is respectfully requested.

Claims 2-34 depend from claim 1 and are patentable over the cited references for at least the same reasons as claim 1.

Since each of the dependent claims depends from a base claim that is believed to be in condition for allowance, Applicants believe that it is unnecessary at this time to argue the allowability of each of the dependent claims individually. However, Applicants do not necessarily concur with the interpretation of the dependent claims as set forth in the Office Action, nor do the Applicants concur that the basis for the rejection of any of the dependent claims is proper. Therefore, Applicants reserve the right to specifically address the patentability of the dependent claims in the future.

The Examiner has provisionally rejected claims 1, 2, 11, 13, 14, 16, 19, 20, 25, 26, 27, 30, 32, 33 and 34 under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 2, 5-7, 10-14 and 27-29 of copending Application Serial No. 11/650,817. Since the rejection is provisional, it is not necessary for Applicant to respond at this time. Applicant reserves the right to respond to the merits of this rejection if and when it is made non-provisional.

Nonetheless, Applicant contends that the same invention double-patenting rejection is improper. In determining whether a statutory basis for a double-patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? (MPEP §804 II.A.). All claims in Serial No. 11/650,817 recite a connection device for the supply of pressure fluctuations which are superimposed on the main aerosol flow, the connection device being formed on the

nosepiece or the flow resistance device such that the pressure fluctuations are introduced directly into the respective nostril of the user's two nostrils. The claims in the present application do not contain this limitation. For this reason, the two applications do not claim the same invention. Accordingly, the same invention double-patenting rejection is improper and should be withdrawn.

Based upon the above discussion, claims 1-34 are in condition for allowance.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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